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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/321,179	10/11/1994	WALTER P. CARNEY	40441CZJPWNP	1590

7590

07/05/2002

JOHN P. WHITE  
COOPER AND DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10112

EXAMINER
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HUNT, JENNIFER ELIZABETH

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/05/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**08/321,179**

Applicant(s)  
**Carney et al.**

Examiner  
**Jennifer Hunt**

Art Unit  
**1642**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 11, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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***Response to Amendment***

1. Acknowledgment is made of applicant's cancellation of claims 2-18. Claim 1 is pending in the application and considered herein.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Claim Rejections/Objections Withdrawn***

3. All objections to and rejections of claim 2 are withdrawn in light of the cancellation thereof.

***Claim Rejections Maintained***

4. The rejection of pending claim 1 for the recitation of the term "corresponds substantially" is maintained for reasons of record.

The previous rejection and arguments stated as follows: *The term "corresponds substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.*

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*The specification discloses that "corresponds substantially provides conservative additions, deletions and/or substitutions." (See page 11, lines 1-2 of the original disclosure). Further applicant argues that one of skill in the art recognizes what extent of additions, deletions, and substitutions would be considered conservative, and further cites a reference which, according to applicant "suggests candidates for conservative substitutions". Applicant's arguments filed 4-5-1996 have been fully considered but they are not persuasive.*

*Initially, it is noted that at page 11 of the specification where "corresponds substantially" is described, the term "conservative" only modifies "additions"; the terms "deletions and/or substitutions" are not modified by "conservative" and thus encompass any deletion and/or substitution. Further, it is still not clear what extent of sequence variation could be tolerated and still meet the limitations of the claims. Even if the term "conservative" described any of the possible sequence modifications, "conservative" is a relative term whose metes and bounds are unclear. Further, the reference cited by applicant is a mere teaching reference which refers to the general structure of amino acids, and does not teach or suggest what would be considered a conservative amino acid sequence modification.*

Applicant now argues that "conservative" modifies substitutions and/or deletions. Applicant next argues that "conservative" is a term of the art which encompasses replacement, addition, or deletion of one or more amino acid residues of a polypeptide which do not alter the biochemical nature of the peptide and allows the peptide to retain substantially the same structure

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and biochemical features. Applicant's arguments filed April 11, 2002 have been fully considered but are not persuasive.

Applicant's assertion that the term conservative is intended to modify the terms substitutions and/or deletions clarifies the record with respect to that grounds of rejection and this grounds if withdrawn. However, with regard to the other grounds, as set forth previously, conservative is a relative term, that while recognized in the art, does not establish clear metes and bounds. The assertion that conservative "encompasses replacement, addition, or deletion of one or more amino acid residues of a polypeptide which do not alter the biochemical nature of the peptide and allows the peptide to retain substantially the same structure and biochemical features" does not further clarify the metes and bounds. It is still not clear what extent of substitutions would be permitted and still meet the limitations of the claim. There is no way to determine how similar the "structure and biochemical features" of a polypeptide must be to meet the limitation "substantially the same" and thus it is not clear how much variation is permitted in a conservative addition deletion and/or substitution and thus it is not clear what would be considered to "correspond substantially" to a polypeptide.

5. The rejection of pending claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention (the written description rejection) is maintained for reasons of record.

As set forth in the previous office action, the claims are broadly drawn to any "p100" which is a neu related protein having a molecular weight from about 97,000 daltons to about 115 daltons which corresponds substantially to the extracellular domain of the human neu gene product, and which is detectable in biological fluid. Thus the claims encompass any compound having a molecular weight in the broad range of about 97,000 daltons to about 115 daltons and which has any number of additions, deletion and/or substitutions in the compound's structure.

Thus the claims are drawn to a large genus of molecules. In the case of small identified amino acid residues claimed with open language, the genus of the polypeptides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of one species, the human neu polypeptide. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polypeptides at the time the instant application was filed.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed.” (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

Applicant is referred to the guidelines for 112, first paragraph, published in the Official gazette and also available on [www.uspto.gov](http://www.uspto.gov).

Applicant argues that the invention is exemplified at page 33, line 20, through page 38, line 21, and that applicants need not establish possession of every embodiment of the invention to satisfy the written description requirement. Applicant’s arguments filed April 11, 2002 have been fully considered but are not persuasive.

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As set forth above, the claims encompass a large, innumerable quantity of polypeptides, which are not limited by sufficient structural requirements such that the invention is adequately described. While the specification provides guidance, it does not provide specific structural limitations which are commensurate in scope with the claims, which encompass virtually any polypeptide in a wide molecular weight range.

6. The rejection of pending claim 1 under 35 U.S.C. 102(b) as being anticipated by Bernards et al., PNAS, Vol. 84, pages 6854-6858, October 1987.

As set forth in the previous office action, Bernards et al. teaches a human *neu* related protein (rat *neu*) comprising the extracellular domain of the *neu* gene product, and which has a molecular weight of about 97,000 daltons to about 115 daltons (100 daltons). (see for example, page 6855 and figure 2). That the protein is detectable in biological fluid is an inherent property of the composition.

Applicant argues that the reference fails to teach every element of the rejected claim. Applicant's arguments filed April 11, 2002 have been fully considered but are not persuasive.

Applicant's argument that the reference fails to teach every element of the claim is not persuasive because applicant has not pointed out what claimed elements are missing from the reference, and as set forth in the previous office action, it is the position of the examiner that the references anticipate the claims.



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7. The rejection of pending claim 1 under 35 U.S.C. 102(e) as being anticipated by Hudziak et al., US Patent 6,015,567.

As set forth in the previous office action, Hudziak et al., US Patent 6,015,567 teaches a substantially purified human *neu* related protein comprising the extracellular domain of a *neu* related gene product and which has a molecular weight from about 95,000 daltons to about 115,000 daltons (see for example, column 1, lines 15-20, column 6, line 55-column 7, line 6, and figure 12 (including description)). That the protein is detectable in biological fluid is an inherent property of the composition.

Applicant argues that the reference fails to teach every element of the rejected claim. Applicant's arguments filed April 11, 2002 have been fully considered but are not persuasive.

Applicant's argument that the reference fails to teach every element of the claim is not persuasive because applicant has not pointed out what claimed elements are missing from the reference, and as set forth in the previous office action, it is the position of the examiner that the references anticipate the claims.

8. The rejection of pending claim 1 under 35 U.S.C. 102(e) as being anticipated by Ring, US Patent 6,054,561.

As set forth in the previous office action, Ring, US Patent 6,054,561 teaches a substantially purified human *neu* related protein comprising the extracellular domain of a *neu* related gene product and which has a molecular weight from about 95,000 daltons to about

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115,000 daltons (see for example, abstract, column 5, lines 24-40, and column 27, lines 1-40).

That the protein is detectable in biological fluid is an inherent property of the composition.

Applicant argues that the reference fails to teach every element of the rejected claim.

Applicant's arguments filed April 11, 2002 have been fully considered but are not persuasive.

Applicant's argument that the reference fails to teach every element of the claim is not persuasive because applicant has not pointed out what claimed elements are missing from the reference, and as set forth in the previous office action, it is the position of the examiner that the references anticipate the claims.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

July 3, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600